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10/534,353	05/09/2005	Jong-Soo Woo	Q87237	4817

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
04/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,353	WOO ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Request for Continued Examination (RCE), Amendments and Remarks filed 5 January 2010 in the matter of Application N° 10/534,353. Said documents are entered on the record. The Examiner further acknowledges the following:

No claims have been added or canceled.

Claims 1 and 10 have been amended to include features that Applicants relied upon in the response to the Final Rejection, mailed 5 October 2009, but that were not recited in the previous amendments to the claims. Said limitations, as discussed herein are directed to "recrystallized particles" of the paclitaxel solution mixture (see **NEW REJECTIONS**). Applicants point to ¶¶[0062]-[0065] in US Pre-Grant Publication N° 2006/0078619 in support of the amendments.

As such, claims 1-10 continue to represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 5 October 2009 since the art which was previously cited continues to read on the amended/newly cited limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US Pre-Grant Publication 2003/0064097) in combination with Kawamura et al. (US Pre-Grant Publication 2004/0219208).

The instant claims remain drawn to a method for preparing a paclitaxel solid dispersion by a supercritical fluid process as discussed in the Office Action, mailed 21 March 2008. The process comprises dissolving a mixture of paclitaxel and additive in a mixed organic solvent. The solvent is next mixed via spraying with a supercritical fluid; the contact of the two solutions resulting in the formation of paclitaxel/additive particles. Any organic solvent remaining on the particles is washed away using additional supercritical fluid. Lastly, the remaining particles are collected. The instantly amended claim 5 is interpreted by the Examiner as reciting a compositional limitation to claim 1 wherein the hydrophilic polymer (e.g. additive) is present in the solution mixture ranging from 1-75% (w/w) prior to the addition of the supercritical fluid.

Patel et al. teach methods for preparing multiparticulate compositions using processes which comprise applying an encapsulation coat onto a substrate (e.g. spray coating and nanoencapsulation) as well as collection of the ensuing particles ¶[0223]. Preparation of the encapsulation coating solution is taught as solubilizing or suspending a composition in a mixture comprising an organic solvent and a supercritical fluid, and which can further comprise additives. Paragraph [0039] teaches paclitaxel as one of the most preferred hydrophobic active ingredients used in the encapsulation coating composition. Paragraph [0257] specifically teaches that multiple organic solvents may be combined as the organic solvent of the coating solutions. Additives are, again, taught as being part of the coating solution composition. Removal of the dispersing medium (e.g. the organic solvent of the coating solution) is taught as occurring at the end of the coating process and in the form of

drying process (e.g. heating, vacuuming, etc.). Recovery of the resulting particles may be accomplished by forming pellets, granules, or spheres, for example ¶[0228].

Patel further teaches additives which include hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), and polyvinyl pyrrolidone (PVP) ¶[0166]. PVP, in particular, is taught as both a binder ¶[0166] and a disintegrant ¶[0174]. Where the coating composition is applied to the particles as a delayed release enteric coating, acrylic polymer additives such as methacrylic acid copolymers as well as other polymers of the Eudragit series (e.g. E, L, S, RL, and RS) are preferably used ¶¶[0190], [0191] and [0202]. The methods discussed at ¶[0224] employ organic solvents which are further defined at ¶[0257] as mixtures of different solvents such as methanol, ethanol, isopropanol, dichloromethane, and ethyl acetate.

Patel does not expressly teach removal (e.g. displacement) of the mixed organic solvent portion of the dispersing medium by washing the coated particles with additional supercritical fluid, but does additionally teach that modifications to the coating process, such as the drying processes, are well known in the art ¶[0226]. Patel also does not expressly teach Applicants' instantly claimed polymer/active weight ratio, percent range of the hydrophilic polymer or the weight ratio of the two organic solvents mixed.

Kawamura et al. teach a process for preparing a sustained-release preparation comprising injectable microcapsules or microspheres ¶¶[0225] and [0226] which comprises an AII antagonist and an anticancer drug (Abstract; claim 1). Paclitaxel is specifically taught as a plant-derived anticancer agent ¶[0154] which may be employed in the formulation. One

such process for preparing said particles or spheres is described in ¶[0259] wherein a compound comprising an AII antagonist and optionally water are added to a solution of additive (e.g. biodegradable polymer) in an organic solvent. Paragraph [0263] teaches different ranges of ratios of the organic solvents (i.e. ratio of dichloromethane to ethanol or methanol). Biodegradable polymers such as PVP are taught as emulsifier additives which may be present at preferable concentration ranging from about 0.01-10% by weight ¶¶[0262] and [0265]. Said solution is then finely dispersible by homogenization or by ultrasound over said particles. The organic solvent used is expressly taught as comprising a mixture of different organic-based solvents ¶[0260] as well as an additive ¶[0261] and/or an emulsifier ¶[0265]. Paragraph [0276] teaches methods for removing water and organic solvents from the coated particles which include evaporation and/or vacuuming. A more specific method for removal of water and organic solvent is expressly taught as being performed using a supercritical fluid in a high pressure gas state ¶[0283]. Collection of the resulting microcapsule particles by centrifugation or filtration is taught in ¶[0277].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a nano-scale paclitaxel solid dispersion (e.g. suspension) by contacting a paclitaxel/additive/mixed alcohol solvent solution with a supercritical fluid, displacing said alcohol solvent with supercritical fluid and recover the resulting particles, as taught and suggested by the combined teachings of Patel and Kawamura.

One of ordinary skill in the art would have been motivated to do this because Patel provides teachings for every aspect of the instantly claimed method except where the organic solvent is removed using supercritical fluid. Patel does teach that at the end of the particle

coating process, the residual dispersing medium, which includes the mixed organic solvent, can be further removed to a desirable level utilizing appropriate drying processes such as vacuum evaporation, freeze drying and heating ¶[0224]. The ordinarily skilled artisan, in view of this teaching and ¶[0226], would have been highly motivated to substitute a gas-propelled process for a suction-based process of evaporating organic solvents, such as the solvent removal method taught by ¶[0283] of Kawamura, particularly since said removal method explicitly teaches using a supercritical fluid in a high pressure gas-state to remove organic solvents (i.e. mixed ethanol and methanol). Furthermore, while Patel does not expressly teach the claimed order of the addition of components of the instantly claimed method, it would have been *prima facie* obvious to a person of ordinary skill in the art that there is no patentable distinction between Applicants' method and the methods taught in the prior art. The selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) Selection of any order of mixing ingredients is also held to be *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (see MPEP 2144.04 (IV)(C.))

Neither of the references explicitly teach polymer/active weight ratio, percent range of the hydrophilic polymer or the weight ratio of the two organic solvents mixed, as claimed by Applicants. The amounts and ratios of specific ingredients in a composition are clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize as is format of oral dosage (i.e. tablet versus capsule). Optimization of parameters, such as the size of granulated particles, is a routine practice that would be obvious for a person of

ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amounts and ratios of each ingredient to add in order to best achieve the desired method as cited in the instant claims. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amounts would have been obvious at the time of Applicant's invention.

Given the mixture process steps taught by Patel as well as the modified, supercritical fluid based, organic solvent evaporation step suggested by Patel and taught by Kawamura, and since both inventions are directed towards methods for solubilizing insoluble drugs such as paclitaxel in small scale, particulate-based drug delivery compositions, it follows that the combined teachings would have afforded the ordinarily skilled artisan a reasonably high expectation of success for producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the combined references, especially in the absence of evidence to the contrary.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Patel and Kawamura as set forth above with respect to claim 1 in combination with Nielsen et al. (USPN 5,716,558).

Neither Patel nor Kawamura teach the temperature or pressure application parameters for the supercritical fluid as set forth by Applicants in claim 10.

Nielsen teaches methods for spraying liquid compositions by using compressed fluids such as carbon dioxide, to form solid particulates and coating powders which may be produced with narrow particle size distributions (Abstract). Nielsen further teaches that compressed carbon dioxide fluid may be sprayed at a temperature of 60°C and a pressure of 1600 pounds/sq. inch (1 bar/14.5 psi; http://onlineconversion.com/pressure.htm) or about 110.3 bar (col. 13, lines 19-26).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have sprayed a supercritical fluid (e.g. carbon dioxide) using Applicants' instantly claimed physical parameters in view of Nielsen's teaching that application of a supercritical fluid to a liquid water-borne polymeric composition comprising a mixed organic solvent produced a dry, collectable powder (Example 9).

PREVIOUS RESPONSE TO ARGUMENTS (FILED 3 JUNE 2009)

Applicants' arguments with regard to the rejection of claims 1-9 under 35 USC 103(a) as being unpatentable over the combined teachings of Patel et al. and Kawamura et al., as well as with regard to the rejection of claim 10 under 35 USC 103(a) as being unpatentable over the combined teachings of Patel et al., Kawamura et al. and Nielsen et al. have been fully considered but they are not persuasive.

Applicants allege that the ordinarily skilled artisan would not be motivated to combine the teachings of the two references on the grounds that each is directed to providing different forms of controlled release of the active agents. It is asserted that Patel is directed to improving the solubility of hydrophobic active ingredients in order to improve delivery of said ingredients, whereas Kawamura is drawn to releasing drugs in a sustained manner.

In response, the Examiner respectfully disagrees and submits that Patel is directed to improving the solubility of hydrophobic compounds (Title), but the compositions prepared by the Patel invention may accomplish the improved solubility using multiple forms of release (e.g. immediate or extended) as evidenced by claim 30. Furthermore, though Kawamura teaches that the formulations prepared are drawn to sustained release, it is also further taught, if not suggested that such a release profile may be adjusted to retain stability and solubility though the simple addition or omission of different pharmaceutically acceptable excipients ¶[0261]. Thus, given that the preparations of the two inventions may both be directed to preparing sustained release formulations having improved or retained solubility of their respective active ingredients, it follows that the ordinarily skilled artisan would have been motivated to combine the teachings of the references in order to arrive at the instantly claimed method.

In response to Applicants' argument that the references fail to show certain features of the subject invention, it is noted that the features upon which Applicants rely (i.e., crystallinity of paclitaxel) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants' remarks concerning the unexpectedly remarkable effects achieved by the instant invention are also considered as being unpersuasive. Applicants draw a comparison to two specific Examples (Ex. 2 and 3) in attempt to demonstrate that the invention of Patel teaches away from the subject invention. The comparison is unpersuasive, first, because Applicants are relying on preferred teachings to teach away. To this, the Examiner

respectively points out that "[t]he use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." Also, "[a] reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments" (MPEP §2123). Thus, the Patel reference does not constitute a teaching away merely on the basis of an Example(s) which employs different constituents which achieve a markedly different release profile.

Furthermore, it appears that Applicants' argue the achievement of unexpected results over the teachings of Patel alone. In response to Applicants' arguments seemingly made against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Lastly, it is not immediately apparent where Applicants traverse the added teachings of Nielsen where it pertains to claim 10, nor is it immediately apparent where claim 10 has been addressed. However, since the rejection of claim 10 does rely on the teachings of Patel and Kawamura, with respect to claim 1, the Examiner interprets concludes that Applicants' remarks against those two references forms the basis of their traversal to claim 10. Applicants are reminded that failure to clearly address rejections made in an Office Action may result in the issuance of a Notice of Non-Responsiveness.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

RESPONSE TO PRESENT ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-9 under 35 USC 103(a) as being unpatentable over the combined teachings of Patel et al. and Kawamura et al. as well as to the rejection of claim 10 under 35 USC 103(a) as being unpatentable over the combined teachings of Patel et al. and Kawamura et al. in further view of Nielsen et al., have both been fully considered but neither is persuasive.

Applicants allege that that the ordinarily skilled artisan would not be motivated to combine the teachings of the Patel and Kawamura references on the grounds that they are respectively drawn to a dosage form having improved solubility versus sustained release. Applicants' allege further lack of motivation to combine in stating that "paclitaxel is embedded in a boilerplate of pharmaceutically active ingredients" and that "Kawamura only teaches removal of water and organic solvent using supercritical fluid".

In response, the Examiner respectfully submits that Applicants appear to be arguing the combination of the references based on two distinct properties (i.e. solubility versus rate of release). It is not clear to the Examiner how the speed with which paclitaxel is released from a dosage form in any way relates to its ability to be dissolved by the system into which it is released. Furthermore, concerning the forms of products that are prepared by both references, Kawamura, as acknowledged by Applicants, is directed to the production of sustained release products. Similarly, ¶[0010] of Patel discloses that solid pharmaceutical compositions having more sustained and complete solubilization upon administration, are a goal of the practiced invention. As such, it stands to reason that since both references are directed to preparing similar dosage forms (e.g. solid sustained release doses), that the

ordinarily skilled artisan would have been motivated to combine the teachings of the references in order to arrive at the instantly claimed method. Furthermore, given the nature of the organic solvents used in the preparation method (e.g. toxicity of organic solvents such as dichloromethane, chloroform, DMSO, etc., to the body), the ordinarily skilled artisan would have been motivated further still by the teachings of Kawamura to incorporate a method step which increasingly diminishes the presence of solvents which are inherently harmful to the human body.

Concerning the "boilerplate" remark, the Examiner respectfully points out that Patel is generally directed to the improved solubility of water-insoluble drugs. Paclitaxel, which is notoriously well-established in the art as being insoluble in water, is listed amongst a smaller group of particularly preferred active ingredients around which the practiced invention is particularly interested ¶[0039].

Lastly, in response to Applicants' argument that the references fail to show certain features of Applicants' invention, it is noted that one of the features upon which Applicants rely (i.e., amount of surfactant present in the composition) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

NEW REJECTIONS

In light of Applicants' amendments, the following rejection is newly added:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Independent claim 1 and dependent claims 2-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1, as presently amended, recites a method "to form recrystallized particles of the mixture of paclitaxel and the pharmaceutically acceptable additive, the recrystallized particles containing paclitaxel of an altered crystallinity". Claim 10, as presently amended also recites "the formation of recrystallized particles".

Contrary to what is indicated in Applicants' response, dated 5 January 2010, the original disclosure provides no support or discussion concerning "recrystallizing" paclitaxel. The Examiner respectfully submits that after carefully examining and reconsidering the instant disclosure in its entirety, specifically ¶¶[0062]-[0065], Applicants, at best, would have support for preparing an initial crystallized form of the drug, but not a re-crystallized form. Since the term "recrystallized" does not appear in the instant disclosure at all, it is accorded its

broadest and most reasonable definition consistent with that which is known in the art (MPEP §2111). Per Merriam-Webster, the term "recrystallize" means "to crystallize again or repeatedly" (http://www.merriam-webster.com/dictionary/recrystallize). In light of the forgoing definition, the Examiner broadly and reasonably interprets Applicants' instantly claimed invention as being directed towards a method for enhancing the solubility of paclitaxel through repeated crystallization of a paclitaxel solution. Support for this method is not found within Applicants' instant disclosure. Thus, given the absence of such a recitation or discussion in the original disclosure, the addition of the aforementioned limitations constitute **new matter**. The Examiner does recognize that the instant invention does support a method for applying a supercritical fluid to a solution comprising paclitaxel, a hydrophilic polymer and a mixed organic solvent to form a particle dispersion (e.g. suspension) of the drug after which the residual solvent is washed away and the resulting particles collected. Herein, and for the purposes of examination on the record, the amended invention will continue to be considered by the Examiner in light of this interpretation

All claims have been rejected; no claims are allowed.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615